

Application No.	Drug	Applicant
NDA 020716	Vicoprofen (hydrocodone bitartrate and ibuprofen) Tablets, 7.5 milligrams (mg)/200 mg.	AbbVie Inc., 1 North Waukegan Rd., North Chicago, IL 60064.
NDA 021692	Ultram ER (tramadol HCl) Extended-Release Tablets, 100 mg, 200 mg, and 300 mg.	Valeant Pharmaceuticals North America LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
NDA 207621	Troxyca ER (oxycodone HCl and naltrexone HCl) Extended-Release Capsules, 10 mg/1.2 mg, 20 mg/2.4 mg, 30 mg/3.6 mg, 40 mg/4.8 mg, 60 mg/7.2 mg, and 80 mg/9.6 mg.	Pfizer Inc., 235 East 42nd St., New York, NY 10017.
NDA 207975	Vantrela ER (hydrocodone bitartrate) Extended-Release Tablets, 15 mg, 30 mg, 45 mg, 60 mg, and 90 mg.	Teva Branded Pharmaceutical Products R&D, Inc., 41 Moores Rd., P.O. Box 4011, Frazer, PA 19355.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of May 2, 2018. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on May 2, 2018 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: March 21, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-06579 Filed 3-30-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Committee on Rural Health and Human Services

AGENCY: Health Resources and Service Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, notice is hereby given that a meeting is scheduled for the National Advisory Committee on Rural Health and Human Services (NACRHHS). This meeting will be open to the public. Information about the NACRHHS and the agenda for this meeting can be obtained by accessing the NACRHHS website at <http://www.hrsa.gov/advisorycommittees/rural/>.

DATES: The meeting will be held on April 16, 2018, from 8:45 a.m.–5:00 p.m. EDT, April 17, 2018, from 8:30 a.m.–5:15 p.m. EDT, and April 18, 2018, from 8:30 a.m.–11:00 a.m. EDT.

ADDRESSES: This meeting will be held at The Saratoga Hilton. The address for the meeting is 534 Broadway Saratoga Springs, NY 12866–2209, (855) 605–0316.

FOR FURTHER INFORMATION CONTACT:

Steve Hirsch, MSLS, Administrative Coordinator, NACRHHS, HRSA, 17W29–C, 5600 Fishers Lane, Rockville, MD 20857, Telephone (301) 443–0835, Fax (301) 443–2803.

SUPPLEMENTARY INFORMATION:

NACRHHS provides counsel and recommendations to the Secretary with respect to the delivery, research, development, and administration of health and human services in rural areas. During the meeting the Committee will examine the issues of Assessing and Mitigating the Effect of Adverse Childhood Experiences and Health Insurance Markets in Rural Areas; conduct site visits to the Adirondack Health Institute in Glens Falls, New York and St. Vincent de Paul Catholic Church in Cobleskill, New York, to visit the Head Start Program; and summarize key findings and develop a work plan for the next quarter. Members of the public will also have the opportunity to provide comments.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018-06651 Filed 3-30-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Vaccine Advisory Committee

AGENCY: National Vaccine Program Office, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human

Services is hereby giving notice that a meeting is scheduled to be held of the National Vaccine Advisory Committee (NVAC). The meeting will be open to the public via teleconference; a public comment session will be held during the meeting.

DATES: The meeting will be held on May 3, 2018, from 10:30 a.m. to 12:30 p.m. ET. The confirmed meeting times and agenda will be posted on the NVAC website at <http://www.hhs.gov/nvpo/nvac/meetings/index.html> as soon as they become available.

ADDRESSES: Instructions regarding attending this meeting will be posted one week prior to the meeting at: <http://www.hhs.gov/nvpo/nvac/meetings/index.html>. Pre-registration is required for members of the public who wish to attend the meeting and who wish to participate in the public comment session. Individuals who wish to attend the meeting and/or participate in the public comment session should register at <http://www.hhs.gov/nvpo/nvac/meetings/index.html>.

FOR FURTHER INFORMATION CONTACT:

National Vaccine Program Office, U.S. Department of Health and Human Services, Room 715H, Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201. Phone: (202) 690–5566; email: nvac@hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to Section 2101 of the Public Health Service Act (42 U.S.C. 300aa–1), the Secretary of Health and Human Services was mandated to establish the National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The NVAC was established to provide advice and make recommendations to the Director of the National Vaccine Program on matters related to the Program's responsibilities. The Assistant Secretary for Health serves as Director of the National Vaccine Program. The public meeting will be dedicated to the deliberation of the draft recommendations written by

the HPV Implementation work group. All agenda items are tentative and subject to change. Information on the final meeting agenda will be posted prior to the meeting on the NVAC website: <http://www.hhs.gov/nvpo/nvac/index.html>.

Members of the public will have the opportunity to provide comments at the NVAC meeting during the public comment periods designated on the agenda. Public comments made during the meeting will be limited to three minutes per person to ensure time is allotted for all those wishing to speak. Individuals are also welcome to submit their written comments. Written comments should not exceed three pages in length. Individuals submitting written comments should email their comments to the National Vaccine Program Office (nvac@hhs.gov) at least five business days prior to the meeting.

Dated: March 27, 2018.

Roula Sweis,

Deputy Director, National Vaccine Program Office.

[FR Doc. 2018-06663 Filed 3-30-18; 8:45 am]

BILLING CODE 4150-44-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; The Genetic Testing Registry

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Institutes of Health (NIH), Office of the Director (OD) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Dina Paltoo, Director, Division of Scientific Data Sharing Policy, Office of Science Policy, NIH, 6705 Rockledge Dr., Suite 750, Bethesda, MD 20892, or call nontoll-free number (301) 496-9838, or Email your request, including your address to: SciencePolicy@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including

whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: The Genetic Testing Registry, 0925-0651, Expiration Date 07/31/2018—EXTENSION, Office of the Director (OD), National Institutes of Health (NIH).

Need and Use of Information Collection: Clinical laboratory tests are available for more than 10,000 genetic conditions. The Genetic Testing Registry (GTR) provides a centralized, online location for test developers, manufacturers, and researchers to voluntarily submit detailed information about the availability and scientific basis of their genetic tests. The GTR is of value to clinicians by providing information about the accuracy, validity, and usefulness of genetic tests. The GTR also highlights evidence gaps where additional research is needed.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 4,198.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
Laboratory Personnel Using Bulk Submission	Minimal Fields	313	25	18/60	2,348
	Optional Fields	313	25	6/60	783
Laboratory Personnel Not Using Bulk Submission ..	Minimal Fields	64	25	30/60	800
	Optional Fields	64	25	10/60	267
Total		377	18,850		4198

Dated: March 24, 2018.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2018-06572 Filed 3-30-18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as

amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning